DEPARTMENT OF HEALTH AND HUMAN SERVICES

TELECONFERENCE MEMORANDUM

Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

February 14, 2007
1 pm EST

Dendreon Participants
Nicole Provost
Elizabeth Smith
David Urdal

FDA participants
Raj Puri
Stephanie Simek
Kimberly Benton
Keith Wonnacott
Thomas Finn

Minutes
We called the sponsor to discuss what manufacturing data they would consider commercial confidential information (CCI) for the purposes of the advisory committee briefing document. The sponsor stated that they will present an overview of manufacturing process and will indicate the release tests but did not want any lot release specifications presented or published and would consider them CCI. We informed them that we thought it would be important to include some data to help the advisory committee be informed about the product. We emphasized that it is a novel product that would be a first in class and has a much different mechanism of action from a classical chemotherapeutic drug. The Sponsor stated they would talk about product heterogeneity using aggregate data and ranges. They will discuss how the data were collected and analyzed for CD54 expression and upregulation similar to their presentation at the Feb 2006 advisory committee on Potency. We said that we agreed not to disclose release specifications, but would like to provide to the advisory committee some data and figures from the BLA submission and/or published literature from the sponsor, and we would let them know what that would include. Specific areas would be the potency assay and characterization of cell types and numbers. The sponsor was generally agreeable to allowing product characterization data use.